K090258

510(k) Summary

AUG 2 5 2009

Name: Talley Medical
1070 E. Wieland Rd.
Lansing, MI 48906

Phone: 888-259-9994 **Fax:** Same
Contact: Jack Van Dyke, President

Trade Name: Venturi™ NPWT v.II Advanced Vacuum System

Common Name: Powered Suction Pump

Device Classification: Class II
Product Code: BTA
Regulation 878.4780
Classification Panel: General and Plastic Surgery

Predicate Devices:		
	Blue Sky Versatile 1 System	K061919
	Prodigy NPWT System	K082415

Device Description: The Talley Venturi™ system consists of a powered suction pump for the application of vacuum for fluid removal. Consumables for use with the pump include collection canister and connection tubing.

Intended Use: Use of the Venturi™ NPWT v.II Advanced Vacuum System is indicated for use in patients that would benefit from a suction device particularly as the device may promote wound healing or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from a patients airway or respiratory support system either during surgery or at the patient's bedside.

Technological Characteristics: The Talley Venturi™ system includes the same type suction pump as the predicate devices, operating at the same pressure ranges. Consumable accessories include collection canister and connection tubing.

Specific Performance Testing: **a)** Canister vacuum test is performed on 100% of production units to check for air-tightness and recognition of sensor pins. Loss of vacuum is measured over a prescribed period. Units pass or fail. **b)** Vacuum pump test is performed on 100% of production sub-assemblies measuring flow and pressure. Tested levels are compared with defined minimum values to determine pass or fail. **c)** Soak test is performed on 100% of assembled production pump units and are run for 48 hours prior to final test. **d)** Final system test is performed on 100% of production units. Tests include all functions and buttons, correct pressure calibration, air tightness, canister recognition, warning systems and alarms, charging system operational.

Conclusion: The Talley Venturi™ NPWT v.II Advanced Vacuum System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Talley Medical
% Mr. Jack Van Dyke
President
1070 E. Wieland Road
Lansing, Michigan 48906

AUG 2 5 2009

Re: K090258
Trade/Device Name: Venturi™ NPWT v.II Advanced Vacuum System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 13, 2009
Received: August 13, 2009

Dear Mr. Van Dyke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) # K090258

Device Name: Venturi™ NPWT v.II Advanced Vacuum System

Indications for Use:

Use of the Venturi™ NPWT v.II Advanced Vacuum System is indicated for use in patients that would benefit from a suction device particularly as the device may promote wound healing or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from a patients airway or respiratory support system either during surgery or at the patient's bedside.

Contraindications for Use:

The Venturi™ v.II NPWT system is contraindicated for use in the presence of:

Necrotic tissue
Untreated osteomyelitis
Fistula
Wounds with malignant tissue
Exposed vasculature, bone, nerves, or organs.

Prescription Use: ___X__ and/or Over the Counter Use: _____
(Part 21 CFR 801 Subparts D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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